

Remarks

Claims 1-3, 6-9 and 12-15 are pending in the subject application. Favorable consideration of the pending claims, in view of the remarks that follow, is earnestly solicited.

The applicant wishes to thank the Examiner for reopening prosecution of the subject application and for the withdrawal of the prior art rejection based on Winitz *et al.*

Claims 1 and 6 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rudman *et al.* in view of Fulks *et al.* and further in view of Dudrick *et al.* Initially, it is noted that the Rudman reference was actually authored by Pearson and Shaw with an opening quote attributed to Rudman, but the applicant will refer to it as the Rudman reference as the Examiner has. The applicant respectfully traverses this ground for rejection because the cited references, either taken alone or in combination, do not disclose or suggest the applicant's advantageous composition, or its use for stimulating muscle growth.

Surprisingly, the current inventor has found that a composition with only four specific amino acids, one of which is arginine, is highly effective in promoting muscle growth. This particular formulation is quite unexpected because, for example, it does not include lysine and, at the time of the invention, those skilled in the art believed that arginine should be combined with lysine.

Specifically, a noted disadvantage associated with L-arginine is that when administered on its own, arginine tends to promote herpes 1 and 2, which gives rise, amongst other adverse effects, to mouth sores and genital discomfort. It is known that L-lysine inhibits the growth of such viruses, and so lysine is conventionally administered with arginine to minimize the onset of herpes. There is no teaching in the cited references that suggests administering arginine in the absence of lysine as is currently claimed.

It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless "there was an apparent reason to combine the known elements in the fashion claimed" by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____ (2007). Furthermore, an applicant's invention is not "proved obvious merely by

demonstrating that each of its elements was, independently, known in the (purported) prior art.”
Id.

The Office Action notes that Fulks *et al.* teach that the “addition of the branched chain amino acids alone decreased protein catabolism as compared to the remaining amino acids (i.e., all but the branched chain amino acids), which did not alter the rate of protein breakdown significantly (col. 1, para.3, p.295).” (Office Action at bottom of page 3 to top of page 4; emphasis added). Thus, as the Office Action acknowledges, Fulks *et al.* teach that the effect of the branched chain amino acids is not improved by the presence of other amino acids. Yet, the Office Action still finds it obvious to add another amino acid. Furthermore, the Office finds it obvious to add only one amino acid, and that amino acid happens to be the one which is present in the applicant’s composition.

It is only the applicant’s disclosure which provides this teaching and the applicant’s disclosure cannot be used to reconstruct the prior art for a rejection under 35 U.S.C. 103. This was specifically recognized by the CCPA in *In re Spinnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969):

The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Sprock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

The Office Action cites the Dudrick *et al.* reference for the proposition that the use of the “L” form of arginine is well known. While this may be true, please note that, as a whole, Dudrick *et al.* teach away from the current invention. Dudrick *et al.* teach a composition that must have at least 5 amino acids (always including lysine) and may have many more. It is very difficult to see how this reference can be part of a rejection wherein a composition having exactly four amino acids is said to be obvious.

It is not permissible when making an obviousness rejection to pick and choose from a reference only the aspects that might tend to support the rejection. Rather, references must be viewed as a whole in terms of what they would have taught the skilled artisan.

In the current case the cited references teach a variety of compositions that are very distinct from the applicant's composition, and there is no apparent motivation to modify those references to arrive at the applicant's very specific composition.

The Supreme Court has stated that "when the (purported) prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 127 S.Ct. 1727 (2007). Here, the claimed invention combines arginine with three other amino acids and without lysine. The state of the art and the cited combination of references (see Dudrick *et al.*, column 2, lines 48-50) taught that lysine should be used with arginine, thus teaching away from the present invention.

The applicant respectfully submits that there is nothing in the cited art, either taken alone or in combination, which would motivate the skilled artisan to produce the specific, unique and advantageous composition as currently claimed. Accordingly, in view of the foregoing remarks, the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103 based on Rudman *et al.* in view of Fulks *et al.* and further in view of Dudrick *et al.*

Claims 1-3 and 6-9 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rudman *et al.* in view of Fulks *et al.* and Dudrick *et al.* and further in view of Boynton *et al.* and Remington's Pharmaceutical Sciences. The applicant respectfully traverses this ground for rejection because the cited references, either taken alone or in combination, do not disclose or suggest the applicant's advantageous composition, or its use for stimulating muscle growth.

The shortcomings of the primary references, as those references relate to the current invention, have been discussed above in detail. Rudman *et al.* teach the skilled artisan very little at all, and certainly the Rudman *et al.* reference does not provide any expectation that the applicant's specific four-amino acid composition would be advantageous. If the Fulks *et al.* reference teaches anything relevant it would be that the branched chain amino acids should be used alone, or at least that there is no benefit from adding other amino acids. This teaches away

from the current invention. Dudrick *et al.* provide an amino acid supplement comprising, as “primary” amino acids, arginine, leucine, valine and lysine (column 2, lines 48-50). Thus, Dudrick *et al.* also teach away from the current invention. Boynton *et al.* do not address these issues at all, nor does the Remington’s reference.

Thus, the secondary references do not cure the deficiencies of the primary references. It is difficult to ascertain how, in the absence of the current applicant’s disclosure, the skilled artisan would pick these references in the first place and, even if these references were chosen, how they would motivate one skilled in the art to arrive at the applicant’s specific composition. In light of the above teachings, it is clear that a person of ordinary skill, given the combination of Rudman *et al.*, Dudrick *et al.*, Boynton *et al.*, and Remington, would not have been motivated to arrive at the current invention. Accordingly, in view of the foregoing remarks, the applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §103.

Claims 12 and 14 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Cerra *et al.* in view of Rudman *et al.* and further in view of Fulks *et al.* and Dudrick *et al.* The applicant respectfully traverses this ground for rejection because the cited references, either taken alone or in combination, do not disclose or suggest the applicant’s advantageous method for stimulating an immune response.

As with the rejections discussed above, it is extremely hard to understand how a reference such as the Cerra *et al.* patent, which discloses a composition with an extensive array of amino acids, can make obvious the use of the applicant’s composition that has only four specific amino acids.

The Office Action suggests that the secondary references would somehow motivate the skilled artisan to remove most of the amino acids from the Cerra *et al.* composition and still expect to achieve an immunostimulatory result. As discussed above in detail, the secondary references provide no such teaching.

Rudman *et al.* teach the skilled artisan very little at all, and certainly the Rudman *et al.* reference does not provide any expectation that the applicant’s specific four-amino acid composition would be advantageous. If the Fulks *et al.* reference teaches anything relevant it would be that the branched chain amino acids should be used alone, or at least that there is no

benefit from adding other amino acids. This teaches away from the current invention and is inconsistent with the teachings of Cerra *et al.* Dudrick *et al.* provide an amino acid supplement comprising, as “primary” amino acids, arginine, leucine, valine and lysine (column 2, lines 48-50). Thus, Dudrick *et al.* also teach away from the current invention.

Furthermore, a skilled artisan at the time of the current invention would not have found it obvious to create a composition with arginine that did not include lysine. Due to the severity of herpes virus infections, a person skilled in the art would have made sure to take precautions that were thought to be necessary to prevent the infections, including using lysine together with arginine.

As noted above, it is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield applicant’s invention does not make the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125,1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, “[b]oth the suggestion and the expectation of success must be founded in the prior art ...” *In re Dow Chemical Co.* 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). One finds neither the suggestion nor the expectation of success in the cited references, either separately or combined. An assertion of obviousness without the required suggestion or expectation of success in the prior art is tantamount to using applicant’s disclosure to reconstruct the prior art to arrive at the subject invention. Hindsight reconstruction of the prior art cannot support a §103 rejection, as was specifically recognized by the CCPA in *In re Spinnoble*, 56CCPA 823, 160 USPQ 237, 243 (1969).

Accordingly, in view of the foregoing remarks, the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103 based on Cerra *et al.* in view of Rudman *et al.* and further in view of Fulks *et al.* and Dudrick *et al.*

Claims 12-15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Cerra *et al.* in view of Rudman *et al.* and further in view of Fulks *et al.* and Dudrick *et al.* and Remington’s Pharmaceutical Sciences. The applicant respectfully traverses this ground for rejection because the cited references, either taken alone or in combination, do not disclose or suggest the applicant’s advantageous composition, or its use for stimulating muscle growth.

As discussed above, the primary references do not disclose or suggest the applicant's advantageous method. The Remington reference does not cure, or even address, the shortcomings of the primary references as those references relate to the current invention. Accordingly, in view of the foregoing remarks, the applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §103.

In view of the foregoing remarks above, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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